REMARKS

Status of the Claims.

Claims 1, 3-4, 7-8, 10-12, 14-18, 21-24, 26-28, 30-36, 44-48, 62-66, 74-79, 93-94, 105-108, and 110-119 are pending with entry of this amendment. Claims 5-6, 9, 13, 19, 20, 25, 29, 37-43, 49-61, 67-73, 80-92, 95-99, and 100-104 were previously cancelled without prejudice to subsequent renewal. Claims 2 and 109 have been canceled with entry of this amendment without prejudice to subsequent renewal, including in a divisional or continuation application. Claims 1, 7-8, 10, 17-18, 21-24, 26-28, 30-36, 74, 106, 108, and 118 are amended herein. Claim 1 has been amended to incorporate the limitations of claim 2, and claim 2 has been canceled without prejudice to subsequent renewal. Claim 108 has been amended to incorporate the limitations of claim 109, and claim 109 has been canceled without prejudice to subsequent renewal. Claim 118 has been amended to specify further that the first polypeptide sequence is capable of directing transcription of said second polypeptide-encoding polynucleotide sequence. All of the amendments to the pending claims introduce no new matter and are fully supported by the specification as filed.

In addition, the specification has been amended to correct several inadvertent typographical errors and to include recited US patent application serial numbers.

Information Disclosure Statement.

Applicants thank the Examiner for notifying them that copies of the cited references enclosed with the Information Disclosure Statement (IDS) mailed on November 6, 2001 have not yet been located. The Examiner has indicated that he can obtain copies of the US patent and international applications cited on the previously submitted PTO Form 1449 and has requested that Applicants re-submit hand-carried copies of the other publications listed in the PTO Form 1449 for the Examiner's review. Applicants are submitting the requested copies by hand delivery to the attention of the Examiner under separate cover. Applicants respectfully request consideration of all references cited in the PTO Form 1449 originally submitted November 6, 2001.

Rejections Under 35 USC § 112.

Claims 10-11, 21-24, 26-28, and 30-36 were rejected under 35 USC § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. Specifically, the Examiner finds that each

of these claims comprises a limitation wherein the claimed nucleic acid comprises a sequence of or difference in sequence with SEQ ID NO: 8 as it corresponds to the consensus sequence in Figures 8A-8I. Office Action, p. 3. The Examiner takes the position that there is no literal or inherent support in the specification as filed for claiming the nucleic acids of the invention as they relate to SEQ ID NO:8 in comparison to the consensus sequence in Figures 8A-8I. *Id.* Although Applicants respectfully traverse the rejection, in an effort to expedite examination, claims 10, 21-24, 26-28 and 30-36 have been amended to delete the phrase included previously. Withdrawal of the rejection is respectfully requested.

Claims 1-4, 7-8, 12, 14-18, 21-24, 26-28, 30-36, 44-48, 62-66, 74-79, 93-94, and 105-119 were rejected under 35 USC § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. Specifically, the Examiner is of the view that claims 1, 7, 8, and 106 comprise the limitation "of at least about 98% [or 99%] sequence identity" and that the "specification doesn't teach exactly what is meant by the term at least about" when applied to percent identity." Office Action, p. 4. Although Applicants respectfully traverse this rejection, noting that one of ordinary skill in the art would have understood the plain meaning of "at least about 98%" or "at least about 99%" in view of the specification, in an effort to expedite prosecution of this application, Applicants have amended claims 1, 7, 8, and 106 to delete the term "about." Withdrawal of the rejection is respectfully requested.

Claim 17-18 were rejected as allegedly being vague and indefinite because "the metes and bounds of the phrase 'higher than the highest level' of the polypeptide encoding sequence are unclear." Office Action, p. 4. This rejection has been overcome by the amendments to claims 17 and 18. Withdrawal of the rejection is respectfully requested.

Claim 74 was rejected as allegedly being vague and indefinite in that there is no clear prior antecedent basis for the term "the subset" in part (b) of the claim. Office Action, p. 4. This rejection has been overcome by the amendment to claims 74. Withdrawal of the rejection is respectfully requested.

Rejections Under 35 USC § 102.

1. **Chapman**

Claims 1-3, 7-8, 12, 14-18, 21-24, 26-28, 30-36, 44-48, 63-66, 74-78, 104-105, and 107-119 were rejected under 35 USC § 102(b) as allegedly being anticipated by Chapman et al. (Nucleic Acids Research 19(14):3979-3986 (1991)) [hereinafter "Chapman"].

The Examiner states that Chapman teaches the construction and characterization of expression constructs comprising ***variations of a 2.4 kb fragment*** obtained for the hCMV Towne strain. The Examiner finds this 2.4 kb hCMV sequence has a 95.8% sequence identity to the polynucleotide sequence SEQ ID NO:8 and a local similarity of 98.8% over residues 335-2099 of the 2.4 kb sequence. The Examiner further finds that the specific fragments characterized by Chapman were shown to drive expression of different coding sequences used as reporters for promoter activity, citing Tables I and II. Office Action, p. 5.

Based on these findings, the Examiner takes the position that:

> Various of the rejected claims comprise limitations where the claimed nucleic acid drives expression of a reporter sequences at different levels relative to expression of the same reporter from a given reference CMV promoter. ***Given the levels of expression for the different constructs characterized by Chapman and given the high degree of identity to the constructs taught in the instant application, one of skill in the art would recognize that the constructs taught by Chapman would necessarily comprise the recited characteristics concerning expression levels in comparison to the reference CMV promoter. Similarly, one of skill in the art would recognize that the constructs of Chapman would express the encoding sequences well enough to induce an immune response in at least expression vectors.*** Because the Office does no have the facilities for examining and comparing the applicant's product with the products of the prior art, the burden is on the applicant to show a novel or nonobvious difference between the claimed products and the products of the prior art (e.g., that the products of the prior art do not possess the same material structural and functional characteristics of the claimed products). See in re Best, 562 1252, 195 USPQ 430 (CCPA 1977).

Id.

Applicants respectfully traverse this rejection for at least the following reasons. To establish a *prima facie* case of anticipation, it must be shown that each and every element as set forth **in each rejected claim** is disclosed, either expressly or inherently, in the single cited prior art reference. *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); *In re Cruciferous Sprout Litigation*, 64 USPQ2d 1202 (Fed. Cir. 2002). "The identical invention must be shown as in complete detail as is contained in th . . . claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Under the principles of inherency, the prior art disclosure need not be express in order to anticipate. A prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference. *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373, 67 UPSQ2d 1664 (Fed. Cir. 2003) (citing *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991)). To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference. *In re Robertson*, 49 USPQ2d 1949 (Fed. Cir. 1999). Inherency may not be established by probabilities or possibilities. That a certain thing *may* result from a given set of circumstances is **not** sufficient for a finding of anticipation. *Mehl/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1365, 52 USPQ2d 1303, 1306 (Fed. Cir. 1999) (emphasis added). For a determination of anticipation to be proper, there must be no genuine dispute that all the limitations of the claimed invention are disclosed, either expressly or inherently, by the allegedly anticipating cited prior art reference. *Hazani v. United States ITC*, 126 F.3d 1473, 44 USPQ2d 1358 (Fed. Cir. 1997). "A limitation or the entire invention is inherent and in the public domain if it is the 'natural result flowing from' the explicit disclosure of the prior art." *Schering Corp.*, 339 F.3d at 1373, 67 UPSQ2d at 1664. Proof that the missing description is inherent in the single prior art reference is required for a finding of anticipation. *Id.*

Applicants respectfully submit that a *prima facie* case of anticipation has not been established for any of the rejected claims. Specifically, it has not been shown that each and every element of claims 1-3, 7-8, 12, 14-18, 21-24, 26-28, 30-36, 44-48, 63-66, 74-78, 104-105, and 107-119 is found -- either explicitly or inherently -- in Chapman. Furthermore, Applicants submit that Chapman does not disclose -- explicitly or inherently -- each element of each rejected claim.

For example, as presently amended, claim 1 specifies an isolated or recombinant nucleic acid comprising a polynucleotide sequence that has at least 98% sequence identity to the polynucleotide sequence of SEQ ID NO:8 or the complementary polynucleotide sequence thereof, wherein said polynucleotide sequence promotes expression of a nucleic acid encoding a polypeptide to which the polynucleotide sequence is operably linked. Applicants respectfully submit that the Office Action has not shown that Chapman teaches or suggests each and every element of claim 1. Specifically, it has not been shown that Chapman teaches or suggests ***any isolated or recombinant nucleic acid comprising a polynucleotide sequence that has at least 98% sequence identity to that of SEQ ID NO:8 or the complementary polynucleotide sequence thereof, wherein said***

polynucleotide sequence promotes expression of a nucleic acid encoding a polypeptide to which the polynucleotide sequence is operably linked.

Figure 1 of Chapman shows a specific polynucleotide sequence comprising a 2.361 kilobase segment of the 5' region of the major immediate-early gene of the human CMV (Towne). Notably, the Examiner concedes that the percent identity between the polynucleotide sequence of SEQ ID NO:8 and the 2.361 kilobase segment of the 5' end of the Towne human CMV IE gene is only 95.8%. Thus, the 2.361-kb segment of the Towne hCMV IE gene disclosed in Chapman does not meet the limitations of claim 1 and thus does not anticipate the nucleic acid particularly defined by claim 1.

The Examiner contends that an *arbitrary subsequence* of the disclosed 2.361-kb segment of the 5' end of the Towne hCMV IE gene, which comprises only nucleotide residues 335-2099 of the 2.361-kb sequence, has a local similarity of 98.8% with the entire polynucleotide sequence of SEQ ID NO:8. Office Action, p. 5. The Examiner appears to base his anticipation argument on this arbitrarily defined fragment of the 2.361-kb sequence. However, Chapman does not teach or suggest that a subsequence comprising residues 335-2099 of the 2.361-kb sequence would ***promote expression of a nucleic acid encoding a polypeptide to which the polynucleotide sequence is operably linked.*** On the contrary, Chapman explicitly teaches that any fragment of the 2.361-kb segment of the Towne hCMV promoter IE gene that includes the first 400 base pairs of the gene have a negative impact on expression of a reporter coding sequence. Chapman, p. 3981. Chapman expressly notes that when the first 400 base pairs were present in expression plasmids, poor expression was observed. Therefore, only fragments excluding the first 400 base pairs were made and characterized. *Id.* at 3982-83. None of the 3 fragments that Chapman characterized -- and upon which the Examiner relies -- included the first 461 base pairs of the 2.361-kb segment of the Towne hCMV promoter IE gene. *Id.* at 3981-3983, Fig. 3, and Table 1. The subsequence comprising nucleotide residues 335-2099 contains a large portion of the 5' end region that Chapman finds to have a negative regulatory role, including the first two NF1 binding sites. Thus, based on the teachings of Chapman, a nucleotide sequence comprising nucleotide residues 335-2099 would not function properly as a promoter.

Simply put, the Examiner has not shown (and Applicants believe cannot show) that Chapman teaches or suggests a nucleic acid comprising a ***polynucleotide sequence that has at least 98% sequence identity to that of SEQ ID NO:8, or the complementary polynucleotide sequence***

thereof, wherein said polynucleotide sequence promotes expression of a nucleic acid encoding a polypeptide to which the polynucleotide sequence is operably linked. As discussed in detail in Applicant's response to the previous Office Action, the three specific fragments of the 2.361-kb segment of the 5' end of the Towne hCMV IE gene that Chapman constructed do not have the same structure as the nucleic acid defined by claim 1.[1] Each disclosed fragment begins at nucleic acid residue 461 of the disclosed 2.361-kb segment. None of the fragments taught by Chapman have the required percent identity as set forth by claim 1. At best, a fragment comprising nucleotides 461-2097 is only about 91% identical to the sequence of SEQ ID NO:8. Furthermore, claim 1 specifies a sequence that has at least 98% sequence identity with the polynucleotide sequence of SEQ ID NO:8, which sequence includes ***an additional 127 nucleotide residues at the 5' end that are expressly excluded from the three Chapman fragments.*** Chapman teaches that these additional nucleotide residues must be excluded, since they relate to NF1 factors that have a negative effect on the expression of an operably liked reporter gene. Thus, the nucleotide sequences of the three Chapman fragments differ dramatically in structure from the nucleic acid of claim 1. Moreover, based on the teachings of Chapman, one of skill would not have concluded that the nucleic acid sequence of claim 1 would have the same or substantially the same functional characteristics as any of the fragments taught by Chapman. In summary, none of the sequences taught by Chapman has the same material structural and functional characteristics as the nucleic acid particularly specified in claim 1.

For at least these reasons, Applicants respectfully submit that a *prima facie* case of anticipation based of Chapman has not been and cannot be established.

Applicants also submit that the Examiner has not shown – and Applicants submit cannot show – that Chapman taught or suggested each and every element of any claim dependent upon claim 1. For example, it has not been shown that Chapman discloses a nucleic acid having at least 99% sequence identity to that of SEQ ID NO:8, or the complementary polynucleotide sequence thereof, that promotes expression of a polypeptide-encoding nucleic acid to which the polynucleotide sequence is operably linked, as explicitly set forth in claim 7. As discussed above,

[1] Fragment B, which includes a promoter/enhancer region and intron A, is a 1636 bp fragment comprising nucleotides 461-2097 (see Chapman's Fig. 3B, Table I, and p. 3980). Fragment C, which begins with nucleotide 461, includes the promoter/enhancer region, but does not include intron A (see Chapman's Fig. 3C and p. 3980). Fragment D, which also begins with nucleotide 461 of the disclosed 2.361-kb segment of the Towne hCMV IE gene, comprises the promoter/enhancer region and a mutant intron A domain (see Chapman's Fig. 3D, p. 3980).

Chapman teaches that a functional promoter sequence fragment of the human Towne hCMV IE gene that is able to properly express an exogenous gene cannot include the first 400 base pairs of the CMV Towne gene. The nucleic acid defined by claim 7 promotes expression of an operably linked polypeptide-encoding nucleotide sequence and has at least 99% sequence identity to the polynucleotide sequence of SEQ ID NO:8. SEQ ID NO:8 includes ***an additional 127 nucleotide residues at the 5' end that are explicitly excluded from the three Chapman fragments.*** The claim specifies a sequence that is at least 99% identical to SEQ ID NO:8. Thus, the nucleotide sequences of the three Chapman fragments differ dramatically in structure from the nucleic acid defined by claim 7. In addition, given Chapman's teachings, one of skill would not have concluded that the nucleic acid sequence of claim 1 would have the same or substantially the same functional characteristics as any of the fragments taught by Chapman.

Nor has the Examiner shown that Chapman teaches the specific additional limitations of any of claims 8, 12, 14-18, 21-24, 26-28, 30-36, 44-48, 63-66, 74-79, 93-94, 105, 107, each of which is ultimately dependent on claim 1. For example, it has not been shown that Chapman teaches or suggests a functional nucleic acid sequence that promotes expression of an operably linked polypeptide-encoding nucleotide sequence that has the specified deletion set forth in, for example, any of claims 21-24, 27, or 28 or the specific sequences defined by claims 30-36. Nor has the Examiner shown that Chapman teaches any of the specific polypeptide-encoding nucleic acids particularly defined by claims 45-48. Nor has it been shown that Chapman teaches any of the specific vectors defined by claim 64. In addition, it has not been shown that Chapman teaches any functional promoter having the specific properties defined by, e.g., claims 3, 8, 14, 17-18, 105, or 107, any assay described by claims 15-16, any cell specified in claims 65-66, or any method particularly defined by claims 75-79.

Furthermore, rejected claims 63, 64, and 94 each depend from claim 62, which the Examiner has not found anticipated by Chapman. Given that claim 62 is not anticipated, claims 63, 64, and 94, which specify additional particular limitations, cannot likewise be anticipated.

Additionally, rejected claim 105 depends from claim 10, which the Examiner has not found anticipated by Chapman. Given that claim 10 is not anticipated, claim 105, which specifies additional particular limitations, cannot likewise be anticipated.

Applicants traverse the rejection of claim 104; claim 104 was previously cancelled and thus this rejection does not apply to claim 104.

Nor has the Examiner shown -- and Applicants submit cannot show -- that Chapman teaches or suggests all of the limitations of independent claims 108, 113, 117, or 118 -- or any claims dependent thereon. For example, it has not been shown (and Applicants believe cannot be shown) that Chapman discloses or suggests an isolated or recombinant polynucleotide comprising a polynucleotide sequence ***having at least 99% sequence identity to the polynucleotide sequence of SEQ ID NO:8 or the complementary sequence thereof, wherein said polynucleotide sequence promotes expression of a nucleic acid encoding a polypeptide to which the polynucleotide sequence is operably linked,*** as set forth in claim 108. As explained in detail above, the nucleotide sequences of the three Chapman fragments differ in structure from the nucleic acid of claim 108, given that SEQ ID NO:8 includes an additional 127 nucleotide residues at its 5' end that are not included in any of the Chapman fragments and the claim specifies a sequence that is at least 99% identical to SEQ ID NO:8. Nor is there any suggestion that any of the 3 Chapman fragments would have the same functional characteristics concerning expression levels as defined by claim 108. Given the teachings of Chapman, one of skill would not have concluded that the nucleic acid sequence of claim 108 would have the same or substantially the same functional characteristics as the fragments taught by Chapman. Applicants submit that Chapman does not teach or suggest the specific sequence defined by claim 108 or any claim dependent thereon. Similar arguments apply to claims 113, 117, and 118 and claims dependent thereon.

For at least these reasons, Applicants submit that the Office Action has not established a *prima facie* case of anticipation of any claim based of Chapman. Moreover, Applicants submit that such a showing cannot be made. Withdrawal of the rejection is respectfully requested.

2. Bebbington

Claims 1-3, 7-8, 12, 14-18, 21-24, 26-28, 44-48, 63-66, 74-78, 104-105, and 107-119 were rejected under 35 USC § 102(b) as allegedly being anticipated by Bebbington (WO 89-01036A1 or WO 89/01036A2) [hereinafter "Bebbington"]. The Examiner states that Bebbington teaches the construction and use of expression vectors comprising the complete 5'-untranslated region including the first introns of the major immediate early gene of human CMV. The Examiner finds that the sequences taught by Bebbington comprise 95.9% sequence identity to SEQ ID NO:8. Further, the Examiner finds that local similarity over about 1.77 kb of the Bebbington promoter sequence reaches levels of up to 97.8% identity with the entire sequence of SEQ ID NO:8. The

Examiner takes the position that "[v]arious of the rejected claims comprise limitations where the claimed nucleic acid drives expression of a reporter sequences at different levels relative to expression of the same reporter from a given reference CMV promoter. Given the levels of expression for the different constructs characterized by Chapman and given the high degree of identity to the constructs taught in the instant application, one of skill in the art would recognize that the constructs taught by Chapman would necessarily comprise the recited characteristics concerning expression levels in comparison to the reference CMV promoter. Similarly, one of skill in the art would recognize that the constructs of Chapman would express the encoding sequences well enough to induce an immune response in at least expression vectors." Office Action, p. 7. The Examiner concludes that Applicants have the burden to show a novel or nonobvious difference between the claimed products and the products of the prior art.

Applicants respectfully traverse this rejection for at least the following reasons. First, Applicants respectfully submit the Office Action has not shown -- and Applicants submit cannot show -- that Bebbington teaches or suggests each and every element of claim 1. Claim 1 specifies an isolated or recombinant nucleic acid comprising a polynucleotide sequence that has ***at least 98% sequence identity to the polynucleotide sequence of SEQ ID NO:8 or the complementary polynucleotide sequence thereof, wherein said polynucleotide sequence promotes expression of a nucleic acid encoding a polypeptide to which the polynucleotide sequence is operably linked.*** No sequence disclosed or suggested in Bebbington meets all of these limitations. The Examiner points out that Bebbington discloses a human CMV promoter sequence having about 95.9% sequence identity to the sequence of SEQ ID NO:8. Clearly, though, that sequence does not serve to anticipate claim 1, since it is not at least 98% identical to the polypeptide sequence of SEQ ID NO:8. The polynucleotide sequence disclosed by Bebbington comprises 2129 nucleotide residues. The polynucleotide sequence of SEQ ID NO:8 is 1676 nucleotide residues in length. It has not been shown that Bebbington teaches or suggests any specific fragment of the disclosed 2129-nucleotide sequence, including a fragment comprising 1676 residues. On the contrary, Bebbington expressly states that his invention is based on the discovery that vectors containing a DNA sequence comprising the promoter, enhancer and *complete or at least substantially complete* 5'-untranslated region of the major immediate early gene of the human CMV upstream of a heterologous gene result in high expression of the heterologous gene product. *See, e.g.*, Bebbington, p. 3, lines 13-28.

Nor has it been shown -- and Applicants submit it cannot be shown -- that Bebbington teaches or suggests any specific fragment of the 2129-nucleotide promoter sequence having the particular functional characteristics expressly set forth in claim 1 -- e.g., promoting expression of an operably polypeptide-encoding nucleic acid. Thus, Bebbington does not teach or suggest a nucleic acid having the specific structure and function expressly defined by claim 1.

For at least these reasons, Applicants submit that the Office Action has not established -- and cannot establish -- a *prima facie* case of anticipation based of Chapman.

Applicants also submit that the Examiner has not shown -- and Applicants believe cannot show -- that Chapman taught or suggested each and every element of any claim dependent upon claim 1. For example, it has not been shown that Bebbington discloses or suggests a nucleic acid having at least 99% sequence identity to that of SEQ ID NO:8, or the complementary polynucleotide sequence thereof, that promotes expression of an operably linked polypeptide-encoding nucleic acid, as explicitly set forth in claim 7. As discussed above, Bebbington discloses a 2129-nucleotide sequence and expressly notes that expression vectors include the *complete or at least substantially complete* 5'-untranslated region of the major immediate early gene of the human CMV. Bebbington does not teach or suggest any specific fragment of the 2129-sequence (such as a fragment comprising 1676 residues as in SEQ ID NO:8) having the particular structural or functional characteristics set forth in claim 7.

Nor has it been shown that Bebbington teaches the specific additional limitations of any of claims 8, 12, 14-18, 21-24, 26-28, 30-36, 44-48, 63-66, 74-79, 93-94, 105, 107, each of which is ultimately dependent on claim 1. For example, it has not been shown that Bebbington teaches or suggests a functional nucleic acid sequence that promotes expression of an operably linked polypeptide-encoding nucleotide sequence that has the specified deletion set forth in, for example, any of claims 21-24, 27, or 28 or the specific sequences defined by claims 30-36. Nor has the Examiner shown that Bebbington teaches any of the specific polypeptide-encoding nucleic acids particularly described by claims 45-48. Nor has it been shown that Bebbington teaches any of the specific vectors defined by claim 64. In addition, it has not been shown that Bebbington teaches any functional promoter having the specific properties defined by, e.g., claims 3, 8, 14, 17-18, 105, or 107, the particular assays set forth in claims 15-16, the cells defined by claims 65-66, or the methods particularly defined by claims 75-79.

Furthermore, rejected claims 63, 64, and 94 each depend from claim 62, which the Examiner has not found anticipated by Bebbington. Given that claim 62 is not anticipated, claims 63, 64, and 94, which specify additional particular limitations, cannot likewise be anticipated.

Additionally, rejected claim 105 depends from claim 10, which the Examiner has not found anticipated by Chapman. Given that claim 10 is not anticipated, claim 105, which specifies additional particular limitations, cannot likewise be anticipated. As Bebbington does not disclose -- expressly or inherently -- the limitations of claim 10, it also does not disclose the limitations of claim 105.

Applicants also traverse the rejection of claim 104; claim 104 was previously cancelled and thus this rejection does not apply to claim 104.

Nor has the Examiner shown -- and Applicants submit cannot show -- that Bebbington teaches or suggests all of the limitations of independent claims 108, 113, 117, or 118 -- or any claim dependent thereon. For example, it has not been shown (and Applicants believe cannot be shown) that Bebbington teaches or suggests an isolated or recombinant polynucleotide comprising a polynucleotide sequence ***having at least 99% sequence identity to the polynucleotide sequence of SEQ ID NO:8 or the complementary sequence thereof, wherein said polynucleotide sequence promotes expression of a nucleic acid encoding a polypeptide to which the polynucleotide sequence is operably linked***, as set forth in claim 108. As explained above, Bebbington discloses only a particular 2129-kb nucleic acid sequence and explicitly points out that expression vectors include the *complete or at least substantially complete 5'*-untranslated region of the major immediate early gene of the human CMV. Bebbington does not teach or suggest any specific fragment of the 2129-kb sequence (such as a fragment comprising 1676 residues as in SEQ ID NO:8) having the particular structural or functional characteristics set forth in claim 108 or any claim dependent thereon. Bebbington does not teach or suggest any specific fragment of the 2129-kb sequence that has at least 99% sequence identity to the polynucleotide sequence of SEQ ID NO:8 and the ability to promote expression of any operably linked polypeptide-encoding gene. Similar arguments apply to claims 113, 117, and 118 and claims dependent thereon.

For at least these reasons, Applicants submit that the Office Action has not established a *prima facie* case of anticipation of any claim based of Bebbington. Moreover, Applicants submit that such a showing cannot be made. Withdrawal of the rejection is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If a telephone conference would expedite prosecution of this application in any way, the Examiner is invited to telephone the undersigned at (650) 298-5809.

Respectfully submitted,

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